

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA

v.

BARRY J. CADDEN, et al.

Defendants.

)
)
)
)
) Criminal Action No. 14-10363-RGS
)
) ORAL ARGUMENT REQUESTED
)
)
)
)

**JOINT MOTION TO EXCLUDE EVIDENCE OF PATIENT HARM
RELATED TO METHYLPREDNISOLONE ACETATE**

Defendants Joseph Evanosky, Gene Svirskiy, Christopher Leary, Scott Connolly, Sharon Carter, Alla Stepanets, Gregory Conigliaro, Kathy Chin, and Michelle Thomas move to exclude all evidence of patient harm related to methylprednisolone acetate (MPA). Unlike Barry Cadden and Glenn Chin, both of whom were charged with 25 acts of second-degree murder in connection with MPA compounded at the New England Compounding Center (“NECC”), none of the remaining defendants in this case is alleged to have had *any* responsibility whatsoever for any MPA-related act or omission that caused harm to patients. They are not alleged to have had any involvement with the production of MPA. Evidence of MPA-related patient harm is thus irrelevant to the charges against them. Moreover, even in the Cadden and Chin trials, where the defendants *were* charged with offenses involving MPA-related harm to patients, this Court recognized the serious risk of unfair prejudice inherent in the MPA-related evidence of patient harm and limited it accordingly.¹ Such evidence would be even more unfairly prejudicial here. It

¹ *E.g.* ECF Docket Entry 834, January 1, 2017 (granting Cadden’s motion to exclude evidence of uncharged deaths and injuries, and allowing evidence “as to the deaths actually charged . . . subject to the court’s rulings on proposed exhibits, particularly those that are deemed unfairly or unduly prejudicial because of their gruesome and/or cumulative nature”).

would also run the risk of seriously confusing the issues and wasting the jury's time on evidence that will not help it decide whether these defendants committed the offenses charged: mail fraud racketeering acts and substantive counts, racketeering conspiracy, conspiracy to defraud the FDA, and Food, Drug and Cosmetic Act (FDCA) violations. This trial will be lengthy and complex as it is, and there is no need to prolong and taint it through the introduction of unfairly prejudicial evidence that is irrelevant to the offenses at hand.

ARGUMENT

I. Evidence of MPA-related patient harm is irrelevant to this trial.

"Evidence is relevant if (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Fed. R. Evid. 401. "Irrelevant evidence is not admissible." Fed R. Evid. 402. In this trial, evidence of MPA-related patient harm is irrelevant and should be excluded.

First, evidence of MPA-related patient harm is irrelevant because the defendants in this trial are not charged with or otherwise accused of having any involvement with the production of MPA. Indeed, it is undisputed that Glenn Chin was the only NECC pharmacist who made the drug. *See, e.g.*, Government closing argument, Chin trial transcript, Oct. 20, 2017, p. 51 (describing Chin as "the only one who made the steroids").

Further, evidence of MPA-related patient harm is irrelevant because the crimes these defendants are charged with do not require any evidence of patient harm for conviction, nor is any MPA-related patient harm alleged in connection with their charged offenses. The defendants here are charged with mail fraud both as racketeering acts and substantively, with a mail fraud racketeering conspiracy (*not* a conspiracy relating to murder), with conspiracy to defraud the FDA in connection with NECC's status as a compounding pharmacy, and with FDCA

violations.² To prove mail fraud, the government has to prove that Svirskiy, Leary, Evanosky, and Scott Connolly “devised and intended to devise a scheme and artifice to defraud NECC’s customers and the patients of those customers, and to obtain money and property by means of materially false and fraudulent pretenses, representations, and promises.” *E.g.* Indictment ¶ 64. To prove the RICO conspiracy charge, the government must prove that Svirskiy, Leary, Evanosky, Carter, and Stepanets “unlawfully and knowingly conspired . . . to conduct and participate, directly and indirectly, in the conduct of the affairs of [an] enterprise through a pattern of racketeering activity . . . consisting of multiple acts of [mail fraud].” Indictment ¶ 73. Similarly, to prove conspiracy to defraud the FDA, the government must prove that Carter, Stepanets, and Gregory Conigliaro “knowingly and willfully conspired and agreed together . . . to defraud the United States . . . of and concerning its right to have its business and its affairs, and particularly the transaction of the official business of the Food and Drug Administration (‘FDA’) conducted honestly and impartially, free from corruption, fraud, improper and undue influence, dishonesty, unlawful impairment, and obstruction.” Indictment ¶ 77. Finally, to prove the FDCA violations, the government must prove that Svirskiy, Leary, Evanosky, Stepanets, Kathy Chin, and Thomas “with the intent to defraud or mislead, caused to be introduced and delivered for introduction into interstate commerce” the specified drugs prepared, labeled, or dispensed in violation of the FDCA. *E.g.* Indictment ¶ 115.

Evidence of MPA-related patient harm is thus irrelevant to whether these defendants committed the charged offenses, unlike in the Cadden and Chin trials, where the defendants were charged with second-degree murder. *E.g., United States v. Brandon*, 17 F.3d 409, 444 (1st Cir. 1994) (affirming exclusion of evidence as irrelevant because it did “not make either of [the

² *Cf.* Memorandum and Order on Restitution re: Glenn Chin, March 20, 2018, ECF No. 1455 (reasoning that patients injected with tainted MPA were not the relevant victims for calculation of restitution because Chin was convicted of mail fraud offenses, which do not require the government to prove patient harm).

party's] theories any more likely to be true"); *United States v. Lamberty*, 778 F.2d 59, 61 (1st Cir. 1985) (finding error in the district court's admission of report to police that defendant postmaster was tampering with packages, prompting a sting operation that led to charges, because such evidence was not "in any way relevant to proving the elements of the counts charged" and "had no probative value," even if jurors "may have been curious as to why the inspectors began their operation").

II. Evidence of MPA-related patient harm would cause substantial unfair prejudice, confuse the issues, and waste the jury's time.

In addition, even if evidence of MPA-related patient harm did have some relevance in this trial, it should still be excluded because any probative value would be substantially outweighed by the danger of unfair prejudice. Fed. R. Evid. 403; *see also* Fed. R. Evid. 403 Advisory Committee Notes (describing "unfair prejudice" as "an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one."). Because the defendants in this trial are not charged with counts where patient harm is an element of the offense, evidence of MPA-related patient harm should also be excluded because it would confuse the issues and waste the jury's time. *Id.*

This case as a whole is the result of a years-long government investigation sparked by a widespread fungal meningitis outbreak linked to injections of NECC-made MPA, with scores of fatalities and hundreds more injured victims. For obvious reasons, charges directly tied to MPA and the outbreak were at the heart of the government's case against Cadden and Chin. But the MPA-related outbreak is not part of the charges against these defendants. The defendants here were charged alongside Cadden and Chin because they worked at NECC, and aspects of that work will be at issue in this trial. They are not charged with killing or injuring anyone, and they

are not mentioned in the portion of the indictment detailing the outbreak-related MPA allegations. *E.g.* Indictment ¶¶ 40–62.

Courts have recognized that permitting evidence concerning patient harm can create unfair prejudice in cases that do not centrally concern that harm. *E.g.*, *United States ex rel. El-Amin v. George Washington University*, 533 F. Supp. 2d 12, 34 (D.D.C. 2008) (evidence of patient harm in a case about billing “would undoubtedly implicate Federal Rule of Evidence 403”); *United States v. Mermelstein*, 487 F. Supp. 2d 242, 257 (E.D.N.Y. 2007) (allegations about patient injury in a case “essentially” about fraud raised concerns of “substantial potential prejudice” and “might improperly influence the jury’s consideration of the fraud charges,” particularly given that “[t]he allegation that defendant’s misconduct caused [patient injury] is a more serious charge than one of fraud”); *United States v. Bainbridge Mgmt., L.P.*, No. 01 CR 469-1, 2002 WL 31006135, at *1–2 (N.D. Ill. Sept. 5, 2002) (excluding as irrelevant and unfairly prejudicial evidence that a codefendant performed unnecessary angioplasties that led to two patient deaths, when defendants were charged with “mail and wire fraud, health care fraud, and racketeering,” and “[t]he crux of the indictment involve[d] a kickback and bribery scheme,” noting that such evidence was “inflammatory and likely to prejudice the jury against the . . . defendants who are not charged with causing the patients’ deaths.”). *Cf. United States v. Gore*, No. 00 CR 737, 2002 WL 1285079, at *1 (N.D. Ill. June 6, 2002) (excluding as unduly prejudicial evidence that defendant’s co-conspirator sold illegal drugs to a person who died by overdose, because the defendant was not charged with that death, or indeed with any injury or death).

Admitting evidence of MPA-related patient harm in this trial would create a substantial risk that jurors will decide fraud and regulatory charges on an improper emotional basis. Jurors

may be so moved by the tragedy that they will hold anyone connected to NECC responsible for it in whatever fashion possible, even if the government has not proven the elements of the crimes charged. *See United States v. Varoudakis*, 223 F.3d 113, 122 (1st Cir. 2000) (“Usually, courts use the term ‘unfair prejudice’ for evidence that invites a jury to render a verdict on an improper emotional basis.”); *cf. United States v. Rodriguez Cortes*, 949 F.2d 532 (1st Cir. 1991) (vacating defendant’s cocaine-related conviction and remanding for new trial due to trial court’s “blatantly prejudicial” admission of an unauthenticated ID card identifying the defendant as Colombian, which had little probative value, “made it more likely that whatever preconceived notions the jury might have had about Colombians and drug trafficking would infect the deliberative process,” and allowed the jury to “find the defendant guilty by reason of his national origin”).

For instance, in *United States v. Ramirez-Rivera*, 800 F.3d 1, 44 (1st Cir. 2015), a case involving a violent street gang, the court held that testimony about “an additional murder” would not cause the jury to have an improper emotional reaction, “[g]iven the nature of this violence-infested case.” By contrast, admitting evidence of patient harm in this case would dramatically change the character of the trial and distract from the actual charges.

Without a government exhibit list for the third NECC-related trial, it is difficult to argue in greater detail about the unduly prejudicial impact of specific evidence. However, based on the gruesome autopsy photos and understandably heart-rending evidence and testimony from the victims’ next of kin offered in the Cadden and Chin trials, it is clear that evidence of MPA-related patient harm would invite the jury to decide this trial based on the very kind of improper emotional basis Rule 403 is intended to prohibit. This was, in fact, one of the arguments advanced for severing the defendants’ trial from that of Cadden and Chin. Here too, it is imperative to keep this evidence out because the risk of unfair prejudice is too high. *See ECF*

Docket Entry 611, July 26, 2016 (denying government’s motion in limine to “admit relevant evidence related to the 2012 fungal meningitis outbreak” against Doug and Carla Conigliaro because, among other reasons, “evidence of the consequences of the outbreak, with the many deaths and grave illnesses that followed, would be highly prejudicial to the defendants and would serve no meaningful purpose.”)

In addition to improperly stirring up emotion, the admission of evidence of patient harm in this trial would also foster the highly prejudicial misconception that these defendants played a role in the meningitis outbreak. After two trials and more than five years of high-profile media coverage of NECC focused on the meningitis outbreak, this misconception may already exist. Barring all evidence of MPA-related patient harm would draw a clear line and distinguish this trial, and these charges, from those faced by Cadden and Chin.

The risk of guilt by association is “perhaps greatest” in this kind of situation, “where the defendant has done little but is closely associated with others already known to have been convicted or, more often, who are co-defendants or alleged co-conspirators whose patent wrongdoing is brought out in detail in the trial.” *United States v. Allen*, 670 F.3d 12, 16 (1st Cir. 2012). *See also United States v. Ofray-Campos*, 534 F.3d 1, 23 (1st Cir. 2008) (quoting *United States v. Izzi*, 613 F.3d 1205, 1210 (1st Cir. 1980), to note that “Guilt by association is one of the ever present dangers in a conspiracy count that covers an extended period.”). As Justice Jackson noted in “his well-known concurrence in *Krulewitch v. United States*”:

A co-defendant in a conspiracy trial occupies an uneasy seat. There generally will be evidence of wrongdoing by somebody. It is difficult for the individual to make his own case stand on its merits in the minds of jurors who are ready to believe that birds of a feather are flocked together.

Id. (citing *Krulewitch*, 336 U.S. 440, 454 (Jackson, J. concurring)).

Similarly, because the defendants here are not charged with any offenses involving MPA-related patient harm, evidence of such harm would also waste the jury's time and confuse the issues, suggesting that this trial is somehow about the meningitis outbreak when in fact it is not. This trial will be long and complex as it is, dealing with evidence actually relevant to the mail fraud, racketeering, racketeering conspiracy, and FDCA charges these nine different defendants face. There is no need to prolong it through the introduction of extremely prejudicial evidence that will not even help the jury decide whether the government has met its burden of proving the elements of the offenses at hand.

CONCLUSION

For the foregoing reasons, this Court should exclude all evidence of MPA-related patient harm from the trial of Evanosky, Svirskiy, Leary, Scott Connolly, Carter, Stepanets, Gregory Conigliaro, Kathy Chin, and Thomas.

Respectfully submitted,

JOSEPH M. EVANOSKY,
By his attorneys,

GENE SVIRSKIY,
By his attorneys,

/s/ Mark W. Pearlstein

Mark W. Pearlstein (BBO #542064)
Dana M. McSherry (BBO #664430)
Jennifer Aronoff (*admitted pro hac vice*)
Evan D. Panich (BBO #681730)
McDERMOTT WILL & EMERY LLP
28 State Street
Boston, Massachusetts 02109-1775
(617) 535-4000
mpearlstein@mwe.com
dmcsherry@mwe.com

/s/ Jeremy M. Sternberg

Jeremy M. Sternberg (BBO #556566)
Christopher M. Iaquinto (BBO #685718)
HOLLAND & KNIGHT
10 St. James Avenue
11th Floor
Boston, Massachusetts 02116
(617) 854-1476
jeremy.sternberg@hklaw.com
christopher.iaquinto@hklaw.com

CHRISTOPHER M. LEARY,
By his attorneys,

SCOTT M. CONNOLLY,
By his attorney,

/s/ Paul V. Kelly

Paul V. Kelly (BBO #267010)
Sarah W. Walsh (BBO #664232)
JACKSON LEWIS PC
75 Park Plaza
4th Floor
Boston, Massachusetts 02116
(617) 367-0025
paul.kelly@jacksonlewis.com
sarah.walsh@jacksonlewis.com

/s/ Raymond Sayeg

Raymond Sayeg (BBO #555437)
KRATTENMAKER O'CONNOR & INGBER P.C.
One McKinley Square
5th Floor
Boston, Massachusetts 02109
(617) 742-1184
rsayeg@koilaw.com

SHARON P. CARTER,
By her attorney,

ALLA V. STEPANETS,
By her attorney,

/s/ Michael J. Pineault

Michael J. Pineault (BBO #555314)
CLEMENTS & PINEAULT, LLP
24 Federal Street
Boston, Massachusetts 02110
(857) 445-0135
mpineault@clementspineault.com

/s/ John H. Cunha Jr.

John H. Cunha Jr. (BBO #108580)
CUNHA & HOLCOMB, P.C.
One State Street
Suite 500
Boston, Massachusetts 02109-3507
(617) 523-4300
cunha@cunhaholcomb.com

GREGORY A. CONIGLIARO,
By his attorney,

KATHY S. CHIN,
By her attorney,

/s/ Daniel Rabinovitz

Daniel Rabinovitz (BBO #558419)
MURPHY & KING, PC
One Beacon Street
21st Floor
Boston, Massachusetts 02108
(617) 423-0400
drabinovitz@murphyking.com

/s/ Joan M. Griffin

Joan M. Griffin (BBO #549522)
P.O. Box 133
Dublin, New Hampshire 03444
(617) 283-0954
griffin@lawjmg.com

MICHELLE L. THOMAS,
By her attorney,

/s/ Michael C. Bourbeau

Michael C. Bourbeau (BBO #545908)
BOURBEAU AND BONILLA, LLP
Building K
80 Washington Street
Norwell, Massachusetts 02061
(617) 350-6565
mike@lawgenie.com

March 27, 2018

REQUEST FOR ORAL ARGUMENT

Defendants respectfully request oral argument on this Motion under Local Rules 7.1(d) and 112.1.

CERTIFICATE PURSUANT TO L.R. 7.1 AND 112.1

I hereby certify that I conferred with Assistant United States Attorney George Varghese in a good faith effort to resolve or narrow the issues raised by this motion pursuant to L.R. 7.1 and 112.1.

/s/ Dana M. McSherry

Dana M. McSherry

CERTIFICATE OF SERVICE

I, Dana M. McSherry, hereby certify that this document was filed on March 27, 2018, via the ECF system, and was sent electronically on that date to the parties' counsel of record.

/s/ Dana M. McSherry

Dana M. McSherry